Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARIA A. GLUCKSMANN and IMMACULADA SILOS-SANTIAGO

Appeal No. 2003-1080
Application No. 09/383,745

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 32 - 59, all the claims remaining in the application.

Claims 32 and 52 are representative of the subject matter on appeal and read as follows:

32. A method for modulating the activity of a polypeptide comprising the amino acid sequence shown in SEQ ID NO:1; the method comprising contacting the polypeptide with a compound under conditions that allow the compound to modulate the activity of the polypeptide, wherein the activity of the polypeptide is modulated in a cell selected from the group consisting of brain cells, spleen cells, lung cells, kidney cells, skeletal muscle cells, liver cells, and heart cells.

52. A method for identifying a compound that modulates the activity of a polypeptide comprising the amino acid sequence shown in SEQ ID NO: 1; the method comprising contacting a cell expressing the polypeptide with a test compound under conditions such that the test compound can modulate the activity of the polypeptide and assessing the activity of the polypeptide to thereby determine if the test compound is a compound that modulates the activity of the polypeptide, wherein the cell is selected from the group consisting of brain cells, spleen cells, lung cells, kidney cells, skeletal muscle cells, liver cells, and heart cells.

The documents relied upon by the examiner are:

Goodwin et al. (Goodwin), "A Regulatory Cascade of the Nuclear Receptors FXR, SHP-1, and LRH-1 Represses Bile Acid Biosynthesis," Molecular Cell, Vol. 6, pp. 517-526 (2000)

Stadel et al. (Stadel), "Orphan G protein-coupled receptors: a neglected opportunity for pioneer drug discovery," Trends in Pharmacological Sciences, Vol. 18, pp. 430-437 (1997)

A reference relied upon by the merits panel is:

Elshourbagy et al. (Elshourbagy) 6,071,722 Jun. 6, 2000

Claims 32 - 59 stand rejected under 35 U.S.C. § 101 (utility) and 35 U.S.C. § 112, first paragraph (enablement). In addition, claims 37 - 46 and 54 - 57 stand rejected under 35 U.S.C. § 112, first paragraph (written description). We vacate all rejections and make a new ground of rejection under 37 CFR § 1.196(b).

Background

The claims on appeal are directed to a method for modulating the activity of a polypeptide comprising the amino acid sequence shown in SEQ ID NO:1 or a method for identifying a compound that modulates the activity of that polypeptide. The polypeptide that comprises the amino acid sequence shown in SEQ ID NO:1 is stated to be a G-protein coupled receptor (GPCR) and is denominated the 14926 receptor protein by appellants. Specification, page 7. The examiner considers that the method

claims under review lack patentable utility because appellants "do not provide a specific utility for the claimed '14926 receptor', as for example no ligand for the receptor, no specific function for the receptor, no specific and substantial signaling activity or cellular response are disclosed." Examiner's Answer, page 3. In reviewing the record of this application, we note that the examiner made Elshourbagy of record, stating that Elshourbagy teaches the nucleic acid and amino acid sequence of a GCPR and that the amino acid sequence of Elshourbagy is "100% identical over its entire length to the instant SEQ ID NO:1 . . . ." Paper No. 11, pages 7-8. The examiner went on to state however, "[Elshourbagy] does not teach the method or the compounds." Id., page 8. There is no dispute on this record that Elshourbagy describes the polypeptide having the amino acid sequence shown in SEQ ID NO:1 of this application. See, e.g., SEQ ID NO:2 of Elshourbagy. Nor is there any dispute that the polypeptide having the amino acid sequence shown in SEQ ID NO:2 of that reference is a GPCR.

What is not clear on this record is the basis for the examiner's statement that Elshourbagy does not teach "the method or the compounds." Paper No. 11, page 8. For example, Elshourbagy states:

> Polypeptides of the present invention are responsible for many biological functions, including many disease states, in particular the Diseases hereinbefore mentioned. It is therefore desirous to devise screening methods to identify compounds which stimulate or which inhibit the function of the polypeptide. Accordingly, in a further aspect, the present invention provides for a method of screening compounds to identify those which stimulate or which inhibit the function of the polypeptide. In general, agonists or antagonists may be employed for therapeutic and prophylactic purposes for such Diseases as hereinbefore mentioned. Compounds may be identified from a variety of sources, for example, cells, cell-free preparations, chemical libraries, and natural product mixtures. Such agonists, antagonists or inhibitors so-identified may be natural or modified substrates, ligands, receptors, enzymes, etc.,

> as the case may be, of the polypeptide; or may be structural or functional mimetics thereof (see Coligan et al., Current Protocols in Immunology 1(2):Chapter 5 (1991)).

Elshourbagy, column 10, lines 46 - 64. Further description of screening methods to ascertain the identity of compounds that modulate the activity of the GPCR of Elshourbagy appears at column 10, line 65 - column 12, line 47 of that reference.

This application was filed on August 26, 1999. The filing date of Elshourbagy is February 16, 1999. This case is stated to be a continuation-in-part of Application No. 09/145,745 filed on September 2, 1998. If the claims on appeal are not entitled to the benefit of the earlier filing date of the stated parent application under 35 U.S.C. § 120, Elshourbagy is prior art based upon its earlier filing date. Alternatively, assuming that one or more of the claims on appeal are entitled to the benefit of the earlier filing date of the stated parent case, we note that Elshourbagy claims priority to two provisional applications dated April 24, 1998 and June 17, 1998. There has been no analysis on this record as to the effective filing date of each claim on appeal. Nor has there been an analysis as to the disclosure of the two provisional applications referenced by Elshourbagy.

Be that as it may, the examiner stated in Paper No. 11 that Elshourbagy is prior art and appellants have not disputed that statement on the record. Thus, we shall proceed in considering the issues raised in this appeal on the basis that Elshourbagy is prior art to the claims on appeal.

On this basis, it becomes apparent that events have overtaken this appeal. Elshourbagy describes the polypeptide having the amino acid sequence shown in SEQ ID NO:1 of this application and describes methods for modulating the activity of that

peptide as well as methods for identifying compounds that modulate the activity of that polypeptide. We note that it is well settled that an anticipatory reference need only teach how to make the claimed invention under review, not how to use the claimed invention under review. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992); In re Hafner, 410 F.2d 1403, 161 USPQ 783 (CCPA 1969). Thus, we need not consider whether the 14926 receptor polypeptide defined in SEQ ID NO:1 of this application and by implication the GCPR described in Elshourbagy have patentable utility under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. We may simply rest our decision on the fact that the claims pending in this case lack novelty.

Under these circumstances, we find it appropriate to vacate the examiner's rejections and make the following new ground of rejection.

New Ground of Rejection Under 37 CFR § 1.196(b)

Claims 32 - 59 are rejected under 35 U.S.C. § 102(e) as anticipated by Elshourbagy.

Each of the independent claims on appeal include within their scope modulating the activity of a polypeptide that comprises the amino acid sequence shown in SEQ ID NO:1 or a method for identifying a compound that modulates the activity of a polypeptide comprising the amino acid sequence shown in SEQ ID NO:1 where the activity of the polypeptide is determined in a kidney cell.

As set forth above, Elshourbagy describes modulating the activity of a polypeptide comprising the amino acid sequence shown in SEQ ID NO:1 or identifying a compound that modulates the activity of that polypeptide. Elshourbagy additionally teaches that the receptors of that invention can be expressed in human embryonic

kidney cells. See, Example 1. Thus, Elshourbagy describes an embodiment that is within the scope of each of the independent claims on appeal.[1]

As to claims 33, 38, 43 and 48 that are directed to the embodiment where the compound is an antibody, we note that Elshourbagy states that antibodies that are immunospecific for the polypeptide of that invention may be produced, column 9, lines 25 - 31.

As to claims 34, 39, 44 and 49 that require modulating the activity of the polypeptide in a brain cell, we note that many of the conditions taught in Elshourbagy to be treatable by the polypeptide of that invention are neurological disorders. Id., column 12, lines 48 - 62. In view of this disclosure of treating neurological disorders, Elshourbagy fairly describes the use of modulating the activity of the present peptide in brain cells.

In regard to claims 35, 40, 45 and 50 that require that the activity of the polypeptide is modulated in a subject having a disorder associated with hyperplasia or inflammation, we also note that some of the disorders stated by Elshourbagy to be treatable involve inflammation, e.g., asthma and allergies. Id. Thus, Elshourbagy fairly describes the subject matter of these claims.

In regard to claims 36, 41, 46, 51, 53, 55, 57, and 59 wherein the activity to be modulated is a G-protein mediated signal transduction activity, we note that Elshourbagy states that the polypeptides to that invention are believed to be GPCRs,

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[1] In regard to other embodiments within certain of the independent claims, e.g., claim 37 which requires the use of a sequence variant of the amino acid sequence shown in SEQ ID NO:1, we point to column 5, lines 36 - 40 of Elshourbagy that describe polypeptide variants of the amino acid sequence of SEQ ID NO:2 of that reference.

column 3, lines 40 - 43, and that GCPRs are involved with signal transduction activity, column 1, lines 34 - 62. Thus, Elshourbagy fairly describes the subject matter of these claims.

Summary

We have vacated the examiner's rejections and instituted a new ground of rejection against claims 32 - 59.

Time Period for Response

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "[a] new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

VACATED; 37 CFR § 1.196(b)

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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